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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,824	10/23/2003	Robert Burgermeister	CRD1061CIP2	6326

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/691,824	Applicant(s) BURGERMEISTER, ROBERT	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayzelden et al (US 2002/0165534 A1) in view of Hampton et al (US 4,940,062) as broadly as structurally claimed.
3. For claims 1, 16, and 26, Hayzelden et al discloses a steerable intravascular device having a deflectable tip, comprising:
 - an inner elongated flexible hollow tubing (22) defining a lumen (28) having proximal (26) and distal portions (24);
 - a flexible helical coil (82) having proximal and distal ends, the proximal end of said helical coil is attached to the distal portion of the inner elongated flexible hollow tubing (as best seen in Figures 2-3);
 - an elongated deflection member (124 and 56) having proximal and distal portions and being slidably disposed within said inner elongated flexible hollow tubing and within said helical coil (as best seen in Figures 5 and 8), the proximal portion of the deflection member being of a cylindrical cross section and the distal portion of said deflection member being flattened or tapered to form a deflection ribbon which extends in a plane (paragraph 43);
 - a retaining ribbon (54) having proximal and distal ends, the proximal end of the retaining ribbon is attached to the distal portion of the inner elongated flexible hollow

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tubing and the retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon; and

- an attachment member (50), a rounded epoxy bead, engaging the distal end of the helical coil, the distal portion of the deflection member and the distal end of the retaining ribbon so that longitudinal movement of the deflection member in a distal direction causes the distal end of the helical coil to be deflected in one direction and longitudinal movement of the deflection member in a proximal direction causes the distal end of the helical coil to deflect in another opposite direction (as best seen in Figure 2).

4. Hayzelden et al discloses the claimed invention except for an outer elongated flexible tubing surrounding the inner elongated hollow tubing so as to define a passageway between the outer tubing wherein the inner elongated flexible hollow tubing and an inflatable balloon mounted on the outer flexible tubing and communicating with the passageway between the outer tubing and the inner hollow tubing. Hampton et al teaches a steerable intravascular device, a balloon catheter, comprising an outer elongated flexible tubing (46) surrounding an inner elongated hollow tubing (48) so as to define a passageway between the outer tubing wherein the inner elongated flexible hollow tubing and an inflatable balloon (47) are mounted on the outer flexible tubing and communicating with the passageway between the outer tubing and the inner hollow tubing (as best seen in Figures 5-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable intravascular device as taught by Hayzelden et al, with the catheter configuration as

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taught by Hampton et al for the purpose of increasing the efficacy of an intravascular device to navigate tortuous vasculature perform a medical procedure.

5. For claims 2, 17, and 27, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the retaining ribbon and the deflection ribbon are capable of being normally biased in a pre-shaped arcuate configuration to thereby cause the distal end of the helical coil to be normally biased in a curved shape as they are formed from a shape-memory metallic alloy (Hayzelden et al paragraph 43).

6. For claim 3, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the proximal portion of said deflection member is of a circular cross section which extends from the proximal portion of the inner flexible tubing to approximately the distal portion of the inner flexible tubing (Hayzelden et al paragraph 43).

7. For claims 4, 7-9, 19-21, 29-31, and 34, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein (a) the proximal end of said retaining ribbon extends from the distal portion of the inner flexible tubing to approximately the distal end of the flexible helical coil (as best seen in Figure 2), (b) the attachment member takes the form of a rounded bead (Hayzelden et al element 50) which contacts the distal end of the helical coil to define a circular surface at the distal end of the coil and the deflection ribbon engages the rounded bead at a location offset from the center of the circular surface of the rounded bead (as best seen in Figures Hayzelden et al 6 and 10), and (c) the distal end of the retaining ribbon engages the rounded bead at a

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location offset from the center of the circular surface in an opposite direction from the offset location of the deflection ribbon (as best seen in Hayzelden et al Figure 6).

8. For claims 5, 18, and 25, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the attachment member takes the form of rounded bead (Hayzelden et al element 50).

9. For claim 6, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the rounded bead is formed with an epoxy material (Hayzelden et al paragraph 30).

10. For claims 10, 22, and 32, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the deflection member (Hayzelden et al element 56) and the retaining ribbon are joined to each other within the rounded bead (as best seen in Hayzelden et al Figure 2).

11. For claims 11 and 23, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the deflection ribbon and the retaining ribbon are formed as a single unitary element (as best seen in Hayzelden et al Figure 2).

12. For claims 12, 24, and 33, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the deflection ribbon and the retaining ribbon are joined to form a generally U-shaped configuration to thereby provide a predetermined spacing between the deflection ribbon and the retaining ribbon and to maintain the deflection ribbon and the retaining ribbon in planes which are parallel to each other (as best seen in Hayzelden et al Figure 2).

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13. For claims 13 and 28, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein flattening an intermediate portion of the deflection member forms the deflection ribbon and flattening the distal portion of the deflection member forms the retaining ribbon (Hayzelden et al paragraph 43).

14. For claims 14 and 35, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the retaining ribbon is of a thickness that is less than the thickness of the deflection ribbon (Hayzelden et al paragraph 43).

15. For claim 15, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the deflection ribbon is capable of being a thickness equal to 0.002 inches and the retaining ribbon is of a thickness equal to 0.0015 inches (Hayzelden et al paragraph 43).

16. For claim 36, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein the proximal portion of the elongated flexible tubing is coupled to a control handle (Hampton et al element 54) and the elongated deflection member is mounted with the control handle for longitudinal movement (as best seen in Hampton et al Figure 11).

17. For claim 37, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein said control handle includes a movable knob (Hampton et al element 57) which is coupled to the elongated deflection member for longitudinal positioning of the deflection member (as best seen in Hampton et al Figure 11).

18. For claim 38, Hayzelden et al in view of Hampton et al disclose a steerable intravascular device, wherein said control handle is coupled to the elongated flexible

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tubing with a release mechanism (62) so that the handle may be removed from the guidewire (as best seen in Hampton et al Figure 11).

Response to Arguments

19. Applicant's arguments filed 01/03/2007 have been fully considered but they are not persuasive. Applicant argues (a) there is no suggestion to combine the teachings of Hayzelden with the teachings of Hampton to construct the instant invention because Hayzelden is concerned with an ablation catheter rather than a balloon catheter; (b) Hayzelden is nonanalogous art because Hayzelden is concerned with an ablation catheter rather than a balloon catheter; (c) Hayzelden teaches away from a passageway defined between inner and outer tubes; and (d) Hayzelden does not teach, suggest or disclose each and every claimed aspect of the invention, specifically arguing there is no teaching of "a flexible helical coil" attached to the distal portion of an inner elongated flexible hollow tubing and no teaching of a "retaining ribbon" having a proximal end attached to the distal portion of an inner elongated flexible hollow tubing. The Examiner disagrees, maintains the rejection, and notes the following:

20. In response to applicant's arguments (a, b, c, and d) against the references individually (specifically Hayzelden), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

21. In response to applicant's argument (a) that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

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combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Hayzelden and Hampton teach steering and guiding members for catheters navigating vasculature.

22. In response to applicant's argument (b) that Hayzelden is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Hayzelden teaches a bidirectional steering catheter for navigating vasculature to provide intravascular treatment.

23. In response to applicant's argument (d) Hayzelden does not teach, suggest or disclose each and every claimed aspect of the invention, specifically arguing there is no teaching of "a flexible helical coil" attached to the distal portion of an inner elongated flexible hollow tubing and no teaching of a "retaining ribbon" having a proximal end attached to the distal portion of an inner elongated flexible hollow tubing, the Examiner disagrees. As broadly as structurally claimed, the ribbon or wire as taught by Hayzelden may have one layer of stainless steel ribbon attached to a distal portion of the inner elongated flexible hollow tubing (paragraphs 11, 32, and 34), moreover a ribbon contains multiple intertwined "a flexible helical coil(s)". As broadly as structurally

claimed, the retaining ribbon has a proximal end attached to the distal portion of an inner elongated flexible hollow tubing via attachment member (50).

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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